DENTAL BOARD[650]

Notice of Intended Action

Proposing rule making related to prescribing standards, continuing education, and disciplinary standards and providing an opportunity for public comment

The Dental Board hereby proposes to amend Chapter 16, "Prescribing, Administering, and Dispensing Drugs," Chapter 25, "Continuing Education," and Chapter 30, "Discipline," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code sections 147.76, 153.33 and 272C.3.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 147.10, 147.11, 153.15A, 153.33, 153.39 and 272C.2.

Purpose and Summary

The primary purpose of these proposed amendments is to make updates in accordance with 2018 Iowa Acts, House File 2377. Additional amendments make updates to and clarify existing rules.

The proposed amendments to Chapter 16 update requirements for prescribing controlled substances pursuant to House File 2377 and update prescribing standards in general.

The proposed amendments to Chapter 25 add requirements for continuing education on opioids, pursuant to House File 2377, and add a provision relating to the number of hours permitted to be claimed for an advanced cardiac life support course.

The proposed amendment to Chapter 30 replaces rule 650—30.4(147,153,272C) with a new rule pertaining to updated disciplinary standards. The proposed amendment clarifies and reorganizes disciplinary standards, adds an opioid-related disciplinary standard as required by House File 2377, and reduces duplicative disciplinary standards.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 650—Chapter 7.

Public Comment

Any interested person may submit written or oral comments concerning this proposed rule making. Written or oral comments in response to this rule making must be received by the Board no later than 4:30 p.m. on April 1, 2019. Comments should be directed to:

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Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Amend rule 650—16.1(124,153,155A) as follows:

650—16.1(124,153,155A) Definitions.

<u>"Authorized delegate"</u> means a licensed or registered health care professional such as a dental hygienist, dental assistant or registered nurse who has obtained PMP log-in credentials. A dental assistant trainee may not serve as an authorized delegate.

"Controlled substance" means a drug or other substance listed in division II of Iowa Code chapter 124.

"Electronic signature" means a confidential personalized digital key, code, or number used for secure electronic data transmissions which identifies and authenticates the signatory.

"Electronic transmission" means the transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment. Electronic transmission includes but is not limited to transmission by facsimile machine and transmission by computer link, modem, or other computer communication device.

"Opioid" means a drug that produces an agonist effect on opioid receptors and is indicated or used for the treatment of pain.

"Prescription drug" means any of the following: (a) a substance for which federal or state law requires a prescription before it may be legally dispensed to the public; (b) a drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements: (1) Caution: Federal law prohibits dispensing without a prescription or (2) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian; or (c) a drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only, or is restricted to use by a practitioner only means a drug, as classified by the United States Food and Drug Administration, that is required to be prescribed or administered to a patient by a practitioner prior to dispensation.

"Prescription monitoring program" or "PMP" means the information program for drug prescribing and dispensing administered by the Iowa board of pharmacy.

650—16.2(153) Scope of authority and prescribing requirements.

- 16.2(1) A license to practice dentistry issued by this board permits the licensee to prescribe, administer, or dispense prescription drugs if the use is directly related to the practice of dentistry and is within the scope of the dentist-patient relationship. Registration with the Federal Drug Enforcement Administration and the Iowa board of pharmacy examiners further extends this privilege to controlled substances.
- 16.2(2) A dental examination must be conducted and a medical history taken before a dentist initially prescribes, administers, or dispenses medication to a patient, except for patients who receive fluoride or silver diamine fluoride dispensed under protocols approved by the bureau of oral and health delivery systems of the department of public health. The examination must focus on the patient's dental problems, and the resulting diagnosis must relate to the patient's specific complaint. The patient's dental record must contain written evidence of the examination and medical history. Prescribing by a licensed dentist must be directly related to the practice of dentistry. A dental examination and medical history must be taken before a dentist initially prescribes, administers, or dispenses a prescription drug to a patient, except for patients who receive fluoride dispensed under protocols approved by the bureau of oral and health delivery systems of the department of public health. A prescription drug prescribed, administered, or dispensed by a licensed dentist must be for a diagnosed condition and be included in a dental treatment plan. The patient's dental record must contain written evidence of the examination and medical history.
- **16.2(3)** On each occasion when a <u>medication prescription drug</u> is prescribed, administered, or dispensed to a patient, an entry must be made in the patient's dental record containing the following information: the name, quantity, and strength of the <u>medication prescription drug</u>; the directions for its use; the date of issuance; and the condition for which the <u>medication prescription drug</u> was used.
- 16.2(4) A patient's dental record that contains an entry pertaining to the issuance of medications must be retained in accordance with 650 27.11(153,272C).
- 16.2(5) 16.2(4) The prescribing, administering, and dispensing of prescription drugs shall be done in accordance with all applicable state and federal laws.
- <u>16.2(5)</u> When controlled substances are purchased, administered, or dispensed, a dentist shall maintain records and accountability in accordance with 657—Chapter 10.
 - 16.2(6) A dentist shall not self-prescribe or self-administer controlled substances.
- 16.2(7) Prescribing, administering, or dispensing controlled substances to members of the licensee's immediate family is prohibited, except for an acute dental condition or on an emergency basis for a dental condition when the licensee conducts an examination, establishes a patient record, and maintains proper documentation.
 - ITEM 3. Rescind rule 650—16.3(153).
- ITEM 4. Renumber rules 650-16.4(153) to 650-16.6(153) as 650-16.3(153) to 650-16.5(153).
 - ITEM 5. Amend renumbered rule 650—16.3(153) as follows:

650—16.3(153) Dispensing—requirements for containers and labeling.

- 16.3(1) Containers. A prescription drug shall be dispensed in a <u>suitable</u> container which meets the requirements of the Poison Prevention Packaging Act of 1970, 15 U.S.C. §§ 1471-1476 which relates to childproof closure, unless otherwise required by the patient. Containers must also meet the requirements of Section 502G of the Federal Food Drug and Cosmetic Act, 21 U.S.C. §301 et seq. which pertains to light resistance and moisture-resistance needs of the drug being dispensed designed to protect its integrity in accordance with all applicable federal and state laws.
- **16.3(2)** Labeling. A label shall be affixed to the container in which a prescription drug is dispensed bearing the following information:
 - 1. to 7. No change.

- 16.3(3) Prescription sample drugs dispensed in the original container or package and provided without charge shall be deemed to conform to labeling and packaging requirements.
 - ITEM 6. Amend renumbered rule 650—16.4(153) as follows:

650—16.4(153) Identifying information on prescriptions Prescription requirements.

- 16.4(1) Prescriptions for Schedule II, III, IV, and V controlled substances must include the name and address of the prescribing dentist and the dentist's federal DEA number. The name and address of the prescribing dentist may be preprinted. Proper security shall be maintained if prescription forms are preprinted. Prior to January 1, 2020, a prescription drug order may be written or transmitted to a pharmacy orally, by fax, or through electronic prescribing in accordance with applicable federal and state laws. A dentist shall take adequate measures to prevent prescription forgery from occurring. Beginning January 1, 2020, all prescription drug orders, including prescriptions for controlled substances, must be electronically prescribed unless otherwise exempted. Beginning January 1, 2020, a dentist who fails to comply with the electronic prescribing mandate may be subject to a nondisciplinary administrative penalty of \$250 per violation, up to a maximum of \$5,000 per calendar year.
- 16.4(2) The dentist's signature on a prescription must be original or an electronic signature, not a copy or stamp, except as the use of electronic signatures may be limited by federal or state law. A dentist may delegate to a licensed dental hygienist or registered dental assistant the preparation of a prescription for the review, authorization, and manual or electronic signature of the dentist, but the dentist is responsible for the accuracy, completeness, and validity of the prescription.
- 16.4(3) On each occasion when medication is prescribed to a patient, the prescription issued to the patient shall contain the following information: the name of the patient for whom the prescription is intended; the name, quantity, and strength of the medication; the directions for its use; the date of issuance; and the name, address, and signature of the dentist issuing the prescription. A dentist shall securely maintain the unique authentication credentials issued to the dentist for utilization of the electronic prescription application and authentication of the dentist's electronic signature. Unique authentication credentials issued to any individual shall not be shared with or disclosed to any other individual.
 - ITEM 7. Amend renumbered rule 650—16.5(153) as follows:
- 650—16.5(153) Transmission of prescriptions Required use of the PMP. A prescription drug order may be transmitted to a pharmacy in written form, orally including telephone voice communication, or by electronic transmission in accordance with applicable federal and state laws and rules. A dentist shall take adequate measures to guard against the diversion of prescription drugs and controlled substances through prescription forgeries. The dentist may authorize an employee to transmit to the pharmacy a prescription drug order orally or by electronic transmission provided that the identity of the transmitting employee is included in the order.
- **16.5(1)** Computer-to-computer transmission of a prescription. Prescription drug orders, excluding orders for controlled substances, may be communicated directly from a dentist's computer to a pharmacy's computer by electronic transmission.
- a. Orders shall be sent only to the pharmacy of the patient's choice with no unauthorized intervening person or other entity controlling, screening, or otherwise manipulating the prescription drug order or having access to it.
- b. The electronically transmitted order shall identify the dentist's telephone number for verbal confirmation, the time and date of transmission, and the pharmacy intended to receive the transmission as well as any other information required by federal or state law or rules.
- c. Orders shall be transmitted only by the dentist or the dentist's employee and shall include the dentist's electronic signature.
- d. The electronic transmission shall be deemed the original prescription drug order provided it meets the requirements of this rule.

- 16.5(1) Before a dentist issues an opioid prescription or dispenses an opioid, a dentist or authorized delegate shall query the PMP. The query shall be performed within 48 hours of a prescription being issued or dispensed and shall be done for each patient, each time an opioid prescription is authorized or dispensed.
- 16.5(2) Facsimile transmission of a prescription. A dentist may request that a pharmacist dispense noncontrolled and controlled drugs, excluding Schedule II controlled substances, pursuant to a prescription transmitted to the pharmacy by the dentist or the dentist's employee. A dentist shall maintain the original prescription, if printed, in the patient's record. A dentist who dispenses a controlled substance is required to report the dispensing to the PMP within one business day in accordance with 657—Chapter 37.
 - ITEM 8. Rescind rule **650—16.7(153)**.
 - ITEM 9. Adopt the following **new** definition of "Opioid" in rule **650—25.1(153)**:
- "Opioid" means a drug that produces an agonist effect on opioid receptors and is indicated or used for the treatment of pain.

ITEM 10. Amend rule 650—25.4(153) as follows:

650—25.4(153) Required continuing education courses.

25.4(1) The following courses are required for all licensees and registrants:

- Mandatory reporter training for child abuse and dependent adult abuse.
- Cardiopulmonary resuscitation. b.
- Infection control. C
- d. Jurisprudence.
- 25.4(2) Mandatory reporter training for child abuse and dependent adult abuse.
- Licensees or registrants who regularly examine, attend, counsel or treat children in Iowa shall indicate on the renewal application completion of two hours of training in child abuse identification and reporting in the previous five years or conditions for exemptions as identified in paragraph "f" of this subrule, 25.4(2)"f," pursuant to Iowa Code chapter 232. Completion of training in this course shall result in two hours of continuing education credit.
- Licensees or registrants who regularly examine, attend, counsel or treat adults in Iowa shall indicate on the renewal application completion of two hours of training in dependent adult abuse identification and reporting in the previous five years or conditions for exemptions as identified in paragraph "f" of this subrule, 25.4(2) "f," pursuant to Iowa Code chapter 235B.
- Licensees or registrants who regularly examine, attend, counsel or treat both children and adults in Iowa shall indicate on the renewal application completion of at least two hours of training on the identification and reporting of abuse in children and dependent adults in the previous five years or conditions for exemptions as identified in paragraph "f" of this subrule, 25.4(2) "f," pursuant to Iowa Code chapters 232 and 235B. Training may be completed through separate courses or in one combined course that includes curricula for identifying and reporting child abuse and dependent adult abuse. Completion of training in this combined course shall result in three hours of continuing education credit. d. to f. No change.
- 25.4(3) Cardiopulmonary resuscitation (CPR). Licensees and registrants shall furnish evidence of valid certification for CPR, which shall be credited toward the continuing education requirement for renewal of the license, faculty permit or registration. Such evidence shall be filed at the time of renewal of the license, faculty permit or registration. Valid certification means certification by an organization on an annual basis or, if that certifying organization requires certification on a less frequent basis, evidence that the licensee or registrant has been properly certified for each year covered by the renewal period. In addition, the course must include a clinical component. Credit hours awarded for certification in CPR shall not exceed three hours of required continuing education hours per biennium. Credit hours awarded

25.4(4) and 25.4(5) No change.

be claimed hour for hour.

for certification in pediatric advanced life support (PALS) or advanced cardiac life support (ACLS) may

25.4(6) The following is required for dentists only.

- a. As a condition of license renewal, a licensed dentist who has prescribed opioids to a patient during the biennium renewal period shall obtain a minimum of one hour of continuing education credit on opioids. This training shall include guidelines for prescribing opioids, including recommendations on limitations of dosages and the length of prescriptions, risk factors for abuse, and nonopioid and nonpharmacological therapy options. This hour may count toward the 30 hours of continuing education required for license renewal. The licensee shall maintain documentation of this hour, which may be subject to audit. If the continuing education did not cover the U.S. Centers for Disease Control and Prevention guideline for prescribing opioids for chronic pain, the licensee shall read the guideline prior to license renewal.
- b. A licensed dentist who did not prescribe opioids during the biennium renewal period may attest that the dentist is not subject to this requirement due to the fact that the dentist did not prescribe opioids during the time period.
 - ITEM 11. Rescind rule 650—30.4(147,153,272C) and adopt the following **new** rule in lieu thereof:
- **650—30.4(147,153,272C)** Grounds for discipline. The following shall constitute grounds for the imposition by the board of one or more of the disciplinary sanctions set forth in rule 650—30.2(153), specifically including the imposition of civil penalties not to exceed \$10,000. This rule is not subject to waiver pursuant to 650—Chapter 7 or any other provision of law.
- **30.4(1)** The board may impose discipline for the following violations related to licensure and registration:
- a. Fraud or deceit in procuring or renewing any license, permit, or registration, including any false or misleading statement of a material fact or omission of information required to be disclosed;
- b. Engaging in the practice of dentistry, dental hygiene, or dental assisting with a lapsed or inactive license, permit, or registration, or engaging in dental radiography with a lapsed or inactive dental radiography qualification;
- c. Engaging in the practice of dentistry, dental hygiene, or dental assisting without a license, permit, or registration, or engaging in dental radiography without a dental radiography qualification;
- d. Employing or permitting an unlicensed or unregistered person or a person with a lapsed or inactive license, permit, or registration to practice dentistry, dental hygiene, or dental assisting;
- e. Encouraging, assisting, or enabling the unauthorized practice of dentistry, dental hygiene, or dental assisting in any manner; or
- f. Failure to prominently display the names of all persons who are practicing dentistry, dental hygiene, or dental assisting within an office.
 - **30.4(2)** The board may impose discipline for the following violations related to ethics:
- a. Fraud in representation as to skill or ability, whether by words or conduct or concealment of that which should have been disclosed, including but not limited to violations of 650—Chapter 26;
- b. Knowingly making misleading, deceptive, untrue, or fraudulent representations in the practice of the licensee's or registrant's profession;
- c. Practicing dentistry, dental hygiene, or dental assisting in a manner that is harmful or detrimental to the public. Proof of actual injury need not be established;
- d. Conviction of a felony or misdemeanor crime if the conviction relates to the practice of the profession;
- e. Improper sexual contact with or making suggestive, lewd, lascivious or improper remarks or advances to a patient or a coworker;
- f. Actions which are abusive, coercive, intimidating, harassing, untruthful, or threatening in the practice of dentistry;
 - g. Obtaining any fee by fraud or misrepresentation;
- *h*. Giving or receiving cash or cash equivalents, or giving or receiving any gifts exceeding nominal value, for referral of patients;
 - i. Failure to transfer patient records to another licensee upon request; or

- *j.* Unprofessional or unethical conduct including, but not limited to, those acts defined by Iowa Code section 153.32 or any violation of 650—Chapter 27.
 - **30.4(3)** The board may impose discipline for the following violations related to the ability to practice:
 - a. Habitual use of drugs or intoxicants rendering the licensee or registrant unfit for practice; or
- b. Practicing dentistry, dental hygiene, or dental assisting while in a state of advanced physical or mental disability where such disability renders the licensee or registrant incapable of performing professional services or impairs functions of judgment necessary to the practice.

30.4(4) The board may impose discipline for the following violations related to patient care:

- a. Willful and gross malpractice;
- b. Willful and gross neglect;
- c. Failure to maintain a satisfactory standard of competency;
- d. Failure to preserve the confidentiality of patient information or accessing any confidential patient information without authorization;
 - e. Practicing beyond training; or
- f. Delegating any acts to any licensee or registrant that are beyond the training or education of the licensee or registrant, or that are otherwise prohibited by rule.

30.4(5) The board may impose discipline for the following violations related to prescribing:

- a. Violating the rules governing prescribing, including any violation of 650—Chapter 16;
- b. Improperly delegating access to the Iowa prescription monitoring program (PMP) to an unauthorized individual:
 - c. Indiscriminately or promiscuously prescribing, administering, or dispensing any drug;
 - d. Failure to check the PMP prior to prescribing an opioid; or
- e. Prescribing opioids in dosage amounts exceeding what would be prescribed by a reasonably prudent prescribing practitioner engaged in a similar practice.

30.4(6) The board may impose discipline for the following violations related to infection control:

- a. Failure to maintain adequate safety and sanitary conditions for a dental office; or
- b. Failure to comply with standard precautions for preventing and controlling infectious diseases and managing personnel health and safety concerns related to infection control, as "required" or "recommended" for dentistry by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services and the Iowa occupational safety and health administration.
- **30.4(7)** The board may impose discipline for the following violations related to reporting, compliance, and other state laws:
 - a. Failure to notify the board of change of address within 60 days;
- b. Failure to report disciplinary action taken by a licensing authority of another state, territory or country, or another licensing authority in this state, within 30 days of the final action by the licensing authority. A stay by an appellate court shall not negate this requirement; however, if the disciplinary action is overturned or reversed by a court of last resort, the report shall be expunged from the records of the board when the board is so notified;
- c. Having a license or registration revoked, suspended, or otherwise disciplined by a licensing authority in any state, territory, or country;
- d. Failure to report any adverse judgment in a professional malpractice action to which the licensee or registrant was a party or any settlement of a claim against the licensee or registrant alleging malpractice;
 - e. Failure to comply with an order of the board;
- f. Violating any provision of Iowa law or rule of the board, or being a party to or assisting in any violation of any provision of Iowa law or rule of the board;
- g. Failure to report any restriction of practice imposed by a hospital, clinic, or other practicing setting;
 - h. Failure to report any misdemeanor or felony conviction within 60 days;
- *i.* Failure to comply with an Iowa practitioner review committee (IPRC) initial agreement or contract;

- *j*. Failure to report to the board any acts or omissions made by other licensees or registrants of the board that may constitute a basis for disciplinary action under the rules of statutory provisions governing the practice of dentistry, dental hygiene, or dental assisting in Iowa; or
- *k*. Failure to report adverse occurrences related to sedation, nitrous oxide inhalation analgesia, and antianxiety premedication pursuant to 650—Chapter 29.
 - **30.4(8)** The board may impose discipline for the following violations related to board investigations:
- a. Knowingly providing false information to the board or an agent of the board during the course of an inspection or investigation or interfering with an inspection or investigation;
 - b. Failure to comply with a subpoena issued by the board;
- c. Failure to fully and promptly comply with office inspections conducted at the request of the board to determine compliance with sanitation and infection control standards or sedation permit requirements;
 - d. Failure to cooperate with a board investigation; or
- e. Retaliating against, threatening, or coercing any person for filing a complaint with the board or cooperating with a board inspection or investigation.
- **30.4(9)** The board may impose discipline for the following violations related to continuing education:
- a. Failure to respond to the board during a continuing education audit, or failure to submit verification of continuing education requirements within the time period provided;
 - b. Knowingly submitting a false report of continuing education; or
 - c. Failure to meet the required continuing education hours per biennium.